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NEW DEVELOPMENTS IN BIOTECHNOLOGY: PATENTING LIFE

Contractor Documents, Part 2

Requirements for Deposit of Microorganisms, Plants and Animals and the Role of the Independent Depository

December 1987

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REQUIREMENTS FOR DEPOSIT OF MICROORGANISMS, PLANTS AND ANIMALS AND THE ROLE OF THE INDEPENDENT DEPOSITORY

THE HISTORICAL DEVELOPMENT OF INDEPENDENT DEPOSITORIES

In 1949 the U. S. Patent Office began recommending to inventors that patent applications for an invention involving a microorganism should include the deposit of the pertinent microorganism with a culture collection. Although not a formal requirement, patent examiners advised applicants that in cases where words alone were not sufficient to describe the invention adequately, a deposit was advisable.

On July 8, 1949, Parke Davis Co. deposited a culture of Streptomyces venezuelae in the American Type Culture Collection (ATCC) which was assigned ATCC number 10712 and is listed in U.S. Patent 2,483,892 (process for the manufacture of chloramphenicol) which issued October 4, 1949.

In August, 1949, American Cyanamid Company deposited a culture of Streptomyces aureofaciens with the Agricultural Research Service Culture Collection (better known as the Northern Regional Research Laboratory (NRRL)). It was assigned NRRL number 2209

and is listed in U. S. Patent 2,482,055 (for the production of aureomycin) which issued September 13, 1949.

These two historic deposits for patent purposes (apparently the first in the world) were forerunners to the current requirement that patent applications for inventions involving microorganisms, plasmids, vectors, cells, plant tissues, seeds and other similar types of material, which are newly isolated, novel, man made, or not generally available to the public on a long-term basis, be supported by a deposit in a recognized public patent depository.

Depositories

A culture depository accepts, maintains and distributes cultures of microorganisms and/or viruses, cells or other genetic-type material. A depository can be public, government, profit or nonprofit.

The main function of a public culture depository is the preservation and distribution of reference cultures which serve as standards for users in the scientific and educational communities.

A culture collection also must improve the strains

in the collection as much as possible, by insuring that they are named or classified correctly and by modern technology, by finding the best methods to preserve the cultures as near as possible to the original state (i.e., unmutated). In addition, public repositories must communicate all of the information learned about the cultures in their care, through publications, through workshops, and other means.

The role of preserving cultures for patent purposes is also an important activity for some public repositories.

In the United States there are currently three depositories for patent purposes (one other depository existed until 1968).

American Type Culture Collection (ATCC), 12301 Parklawn Drive, Rockville, Maryland 20852.

ATCC is a private, not-for-profit, institution organized in 1925 for the purposes of acquiring, preserving and distributing cultures of microorganisms to scientists. Its Board of Directors is composed of scientists elected from 19 major scientific societies in the U.S. and two in Canada. Since July, 1949, the ATCC has served as a depository for patent purposes (the first formal recognition of the ATCC for patent

deposit purposes was provided in a 1952 letter from the U. S. Patent Office). In 1949 only bacteria and fungi were accepted for patent purposes. The Depository, responding to the needs of the "patent community," has grown to include many other types of genetic material. It now holds an estimated 8,000 deposits for patent purposes which include algae, animal viruses, bacteria, cell lines, fungi, hybridomas, oncogenes, plant viruses, plasmids, plant tissue cultures, phages, protozoa, seeds, and yeasts. It was the first internationally approved depository for patent purposes by the World Intellectual Property Organization in January 1981. In the beginning ATCC did not charge for deposit of a culture for patent purposes, but since 1952 a fee has been charged for the deposit and distribution of cultures deposited for patent purposes. The current fee is $670.00 for 30 years maintenance and viability test.

Northern Regional Research Laboratory (NRRL).

NRRL was established in 1940 as part of the U. S. Department of Agriculture, for microorganisms of agricultural and industrial importance. Since 1949 it has also served as a patent depository for nonpathogenic microorganisms which are not difficult in

their growth requirements. There are approximately 3,000 cultures on deposit. In the beginning no fee was charged for patent deposits at NRRL, but since November 1983 a fee has been charged for the deposit and distribution of cultures deposited for patent purposes. The current fee is $500.00 for 30 years maintenance and viability test. The NRRL was approved in 1981 as an internationally accepted patent depository by the World Intellectual Property Organization.

Institute of Microbiology, Rutgers University (IMRU).

IMRU accepted its first deposit for patent purposes in May, 1952, and served as a depository for bacterial cultures involved in patents until March, 1968. At that time IMRU discontinued the acceptance of cultures for patent purposes. On November 30, 1978, all cultures on deposit at IMRU for patent purposes were transferred to the ATCC where they are currently maintained.

In Vitro International Inc. (IVI).

IVI was incorporated in 1983 as a for-profit company for the purpose of accepting cultures for patent purposes. It was approved in November 1983, as an internationally accepted depository for patent purposes by the World Intellectual Property Organization. A fee

of $610.00 is charged for the 30 years maintenance and viability test of a culture deposited for patent purposes. There are approximately 100 cultures on deposit.

In Vitro is the first for-profit repository for patent deposits. Generally, the necessity for many types of professional expertise to handle the various culture deposits makes it an unprofitable venture.

It would be quite costly to develop a depository solely for patent cultures. The number of deposits now or likely for the future are not sufficient to require profit depositories.

GENERAL REQUIREMENTS FOR DEPOSIT OF MICROORGANISMS, PLANTS AND ANIMALS AS THEY RELATE TO THE APPLICATION FOR A PATENT

U. S. patents in microbiology had their beginning in 1873 when the first patent dealing with microbiology was granted to Louis Pasteur (U.S. Patent 141,072) and the patent included a claim to a biologically pure culture of a microorganism. Since the granting of that historic patent to the Pasteur Institute, many hundreds of patents have been issued on microbiological processes.

The practice of making deposits of microorganisms began in 1949 with the first historic deposits at the ATCC and NRRL and was followed until 1970 when it was challenged in the U.S. Court of Customs and Patent Appeals (CCPA) (In re Argoudelis, CCPA 1970). The CCPA, in a landmark decision, approved this practice.

U.S. Patent and Trademark Office (USPTO)

The first published guidelines by the USPTO on the deposit of microorganisms for patent purposes appeared in the Official Gazette in 1971 (Wahl, 1971) in which the procedure accepted in 1970 "In re Argoudelis, et al" for meeting the requirements of 35 U.S.C., 112 was adopted by the Patent Office as complying with the statutory requirements of 35 USC Section 112, first paragraph, for an adequate disclosure of the microorganisms required to carry out the invention as follows:

> "(1) the applicant, no later than the effective U.S. filing date of the application, has made a deposit of a culture of the microorganisms in a depository affording permanence of the deposit and ready accessibility thereto by the public if a

patent is granted, under conditions which assure (a) that access to the culture will be available during pendency of the patent application to one determined by the Commissioner to be entitled thereto under Rule 14 of the Rules of Practice in Patent Cases and 35 U.S.C. 122, and (b) that all restrictions on the availability to the public of the culture so deposited will be irrevocably removed upon the granting of the patent; (2) such deposit is referred to in the body of the specification as filed and is identified by deposit number, name and address of the depository, and the taxonomic description to the extent available is included in the specification; and (3) the applicant or his assigns has provided assurance of permanent availability of the culture to the public through a depository meeting the requirements of (1). ..."

In 1975 an important decision was reached in Feldman v. Aunstrup (CCPA 1975), in which the court held that the use of a heretofore unknown strain in an old process was patentable due to the prior unavailability of the strain. **Feldman v. Aunstrup** also expanded the scope of the type of depository USPTO

would accept, i.e., private, nongovernmental, even for-profit type depositories.

In 1977 the "Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure" was established. The Treaty requires contracting states which allow or require the deposit of microorganisms for the purpose of patent procedure to recognize for such purposes the deposit of a microorganism with any International Depository Authority (IDA). The depository authority must be approved by the World Intellectual Property Organization (WIPO). No contracting state may require compliance with requirements different from or additional to those which are provided in the Treaty.

The Treaty was modified in 1980 and the United States became a contracting party on August 19, 1980, on which date the Treaty became effective. As of 1987 there are 21 countries party to the Treaty. There are 15 International Depository Authorities approved under the Treaty (see Table 2-A). The USPTO has accepted the requirements of the Treaty as meeting deposit requirements.

Although patent applicants attempted to claim the microorganism <u>per se</u>, the Patent Office prior to 1980

rejected the claim to the microorganism per se. The rationale was that since the microorganism was living, it was a product of nature and, therefore, not patentable.

In June, 1980, the now famous Chakrabarty invention on man-made plasmid-injected Pseudomonas was found patentable by a narrow vote (5-4) of the U. S. Supreme Court (Diamond v. Chakrabarty, (USPQ 193, 1980) as a composition of matter under 35 USC Section 101. There is no longer a distinction between living and nonliving compositions of matter as long as they are man-made.

In 1985 another landmark decision, In re Lundak, (Fed. Cir. 1985), was handed down by the Court of Appeals for the Federal Circuit. The USPTO had refused to grant a patent to Lundak because the claimed cell line was not deposited with a recognized depository as of at least the filing date of the patent application. The Court concluded that the only requirement during the pendency of the patent application was that a specimen of the cell line be made available to the Patent Office should the Patent Office so request, as authorized by 35 U.S.C. 114. The Court held Lundak's deposit with the ATCC, which was made a few days after

filing but prior to issuance of his patent, and which is referred to in his specification, met the statutory requirements.

A few days after the Lundak decision, the PTO Board of Appeals and Interferences handed down another important decision, that plants are appropriate subject matter on which a utility patent can be granted (Ex parte Hibberd, 1985, PTO Board of Patent Appeals and Interference. The Patent Office theory that the protection afforded by the Plant Variety Protection Act or under the Plant Patent Act preempted protection for plants under 35 U.S.C. 101 was rejected.

The most recent decision affecting biotechnology patenting was issued by the Board of Patent Appeals and Interferences on April 3, 1987 (Ex parte Allen, 1987). This decision held that claimed polyploid oysters are nonnaturally occurring manufactures of compositions of matter within the meaning of 35 U.S.C. 101. Accordingly, the Patent and Trademark Office is now examining claims directed to multicellular living organisms, including animals. To the extent that the claimed subject matter is directed to a non-human, nonnaturally occurring manufacture or composition of matter -- a product of human ingenuity -- such claims

will not be rejected under 35 U.S.C. 101 as being nonstatutory subject matter.

In view of the above decisions and the scientific advances in biotechnology (i.e., genetic engineering), the United States Patent and Trademark Office (Federal Register, 1987) has proposed rule making for deposit of biological materials for patent purposes (see Appendix A).

These rules, if adopted formally by the PTO, will assist the inventor and the depository in defining the deposit requirements of the USPTO. The USPTO has received only 18 comments on the proposed rules, ranging from the view that rigid rules may not be desirable, to the need for a depository for plants. The majority of the comments were directed to the conditions of the release or availability of a culture once a patent is granted. There appears to be no major objection to the proposed rules. There is, however, one problem which has not been addressed by these rules, although it has been brought to the attention of the USPTO on several occasions.

Immediately upon receipt of a culture, a depository should, and under proposed rules must, check viability of the culture. If it is a living culture or

capable of replicating, a certificate of deposit and a depository number is provided to the inventor. The proposed USPTO rules permit replacement of the culture by the inventor for two reasons: (1) if the depository later finds that it is no longer viable or, (2) for whatever reason cannot provide a sample of the culture.

However, under even the proposed rules, the depository has no responsibility to test or provide evidence that the deposited material performs any function described in the patent application, or to test the culture for purity. Because the rules do not specify whether a replacement is allowed for an initially deposited culture which is later found to be contaminated or does not perform the function described in the patent, many depositors may argue that a depository can accept a replacement, with deposit date of the original culture, for these purposes. Already attorneys have put forth the interpretation that if a culture does not perform the function described in the patent, the culture should be considered nonviable, and a replacement permitted. This presents a dilemma for a depository. ATCC has passed these concerns on to the USPTO. **This problem should be resolved.**

ROLE OF THE INDEPENDENT DEPOSITORY IN FACILITATING PROVISIONS OF PATENT LAW GOVERNING SPECIFICATION OF THE PATENT APPLICATION

The role of the depository is intended to be an objective source independent of the patent applicant/patentee for the maintenance and distribution of cultures involved in pertinent patented inventions. Many depositories know little about the legal requirements of the patenting system. However, in order for a depository to facilitate the deposits of cultures it has become necessary to know the legal requirements for deposit in the U.S. and internationally. For instance, in the U.S. it is possible to make a deposit up until the date a patent is granted, but if an applicant wishes to claim the U.S. filing date as his priority date when filing in other countries, it is necessary for the deposit to have been made by the date of filing of the patent application in the U.S. Moreover, in many cases a depository is asked to advise inventors on whether a deposit is necessary in order to disclose the best mode of carrying out the invention, as required in the U.S., or to disclose how to make and how to use the

invention, i.e., an enablement of the invention, as required in almost all countries. It is not the role of the depository to provide such legal advice.

In some cases, the patent culture depository is the first place the inventor contacts when he/she believes he/she has made a patentable invention. Inventors often times do not understand the role of the depository.

In order to assist biotechnology patenting, one depository has arranged an annual "Biotechnology Patent Conference" at which U. S. patent attorneys, USPTO patent agents, patent attorneys from Japan and Europe, and ATCC patent depository staff acquaint inventors and attorneys practicing in this field with the most up-to-date information on patent disclosure and claim requirements, as well as depository patent practices.

Many depositories have had to expand the types of material accepted and to develop expertise in the maintenance and growing of materials never before anticipated.

In 1982, for instance, no depository in the world accepted plant tissue cultures for patent purposes. In response to this need, the ATCC developed the expertise to maintain a collection of plant tissue cultures, and

in 1983 began accepting this material, as well as seeds, for patent purposes.

Depositories facilitate the deposit of cultures for patent purposes by providing current information on deposit requirements, and by developing the expertise necessary to maintain new types of material as needed.

INDEPENDENT DEPOSITORIES IN THE U.S. AND NUMBERS AND SCOPE OF SAMPLES OF MICROORGANISMS, PLANTS AND ANIMALS HELD

There are currently three recognized depositories in the U.S. which accept and maintain cultures to meet U.S. Patent Office requirements. The names, addresses, types of deposits accepted and numbers of such deposits are included in Table 1-A.

Each of the depositories is approved by the World Intellectual Property Organization (WIPO) as International Depository Authorities meeting the requirements of the Budapest Treaty.

None of the depositories at this date accepts animal life forms. The ATCC has been asked by at least one inventor if it will accept an animal form, and is currently considering the consequences of doing so.

CONSIDERATIONS RELATED TO THE DEPOSITING OF MICROORGANISMS, PLANTS, AND ANIMALS

GENERAL METHOD OF PRODUCING AND MAINTAINING SAMPLES OF MICROORGANISMS, PLANTS AND ANIMALS

Any depository approved by the WIPO meets the requirements of the Budapest Treaty and is, therefore, acceptable for U.S. Patent and Trademark Office purposes.

Table 2-A provides a list of all WIPO approved depositories, their addresses, the fees charged for maintenance and distribution of cultures, and the kinds of cultures accepted. There are 15 WIPO approved depositories, three of which are located in the U.S.

In most cases, the procuring of cultures is easily accomplished by the requesting of the culture in question and the payment of the fee published by the Depository. In a few cases the procuring of cultures is more complicated and time-consuming. For example, the patent depository in Japan requires a number of forms and a power of attorney. Table 3-A describes the method for requesting a culture from the Fermentation Research Institute in Ibaraki-ken, Japan.

In a few instances depositories in other countries have denied access to a culture even though it was cited in a U.S. patent as on deposit, and therefore legally available without restriction to the public, as available from that depository.

The U.S. Commerce Department requires an export license before one may export many types of microorganisms (includes most bacteria and viruses) outside the United States. The depository must apply for the license, which sometimes delays the request for two to three weeks. In some cases the U.S. Department of Agriculture or the U.S. Department of Health and Human Services requires an import permit before allowing import cultures into the U.S. This can also delay the receipt of cultures from outside the U.S.

Generally, cultures involved in the patenting process must be made available either when the patent is issued (as under the U.S. patenting system) or when the patent application is published (as under the European patenting system). If an issued patent cites the use of a culture deposited at a patent depository, the depository is obligated to make the culture available to the public upon request and payment of a quoted fee. The European Patent Office (EPO) must

certify one's right to a culture if the patent application has been published in its office, but the requestor must agree to use the culture for research purposes only and not to redistribute it to another party, unless this requirement has been waived by the depositor. Also under the EPO system, an inventor may choose an option that requires the culture to be made available through an expert (experts are approved by the EPO President) and not directly to the party who has requested it.

The availability of samples from U.S. depositories for cultures involved in the patenting process is straight-forward. If the depository number and the U.S. Patent number are known, the culture may be requested, and it has, to date, always been made available. Obtaining cultures from depositories outside the U.S. can be delayed and, since the depositories are not always knowledgeable of U.S. patent requirements, on occasion requests have been denied. There have been few reasons given for such denial. A collection in the USSR, for instance, inferred that someday, perhaps, the requested culture would be made available. Several years later it still has not been made available. Another collection in The Netherlands simply stated a

requested culture was not available, with no reason. There is no record of a U.S. depository ever denying access to someone eligible to receive a culture.

There would appear to be a need for the Patent Office to establish a mechanism to investigate and take appropriate action when a depository denies access to a culture cited in a U. S. Patent when that deposit was made to satisfy patent requirements.

METHODS OF ASSURING ACCESS TO SUCH SAMPLES DURING THE PENDENCY AND FOLLOWING THE GRANTING OF PATENT APPLICATION

The Budapest Treaty and the U.S. Patent and Trademark Office require a culture to be maintained for 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. In addition, the U.S. Patent and Trademark Office requires the culture to be on deposit for at least the enforceable life of the U. S. Patent plus six years for statute of limitations on infringement.

The 30 year maintenance requirement, if deposit is made at the time of filing for a patent, would appear to assure that the culture would be available for a

period of time after a patent expired, in order that the public have reasonable access after patent expiration, since the normal life of a U.S. patent is about 17 years (an additional six years for statute of limitations on infringement). However, when the culture is deposited years before a patent application is filed, there could be cases where after the patent expires, the culture could be discarded immediately. It would appear that 30 years after filing for a patent, rather than after making a deposit, would be a better way of assuring access to the culture, both during the life of the patent and afterwards.

Depositories approved by WIPO must post a bond to ensure that, in the event of the default of a depository, sufficient funds would be available to transfer patent cultures to another depository.

Inventors are required to agree to replace cultures if they are lost, or die, during the "30 years plus five" deposit period. In cases where an inventor or his/her heirs or assignees are unable to replace a culture, the patented invention may not be valid. In most cases an invention is assigned to a company or institution, and replacements are a corporate responsibility, not an individual one. In rare cases,

the nonpayment of a maintenance fee to a depository could result in the return of the culture to the inventor, thereby placing the patent in jeopardy. In most cases the fee is paid in advance, thereby alleviating the problem. There appear to be adequate safeguards for the safekeeping of a "patent" culture during the required storage period.

POSSIBLE METHODS OF DEPOSIT FOR PATENTED PLANTS AND ANIMALS

In 1985 the PTO Board of Appeals and Interferences handed down the important decision that plants can be protected with a utility patent. Ex parte Hibberd (PTO Bd. App. Int'f 1985). The patent examiner had rejected the claims under the rationale that the protection afforded by the Plant Variety Protection Act, or under the Plant Patent Act preempted protection for plants in a utility patent under 35 U.S.C. 101.

Inventors are now depositing seeds and plant tissue cultures to support patent applications. The first plant tissue deposit at the ATCC was in 1983, and the first seed deposit in 1985. Since that time approximately 40 plant tissue and seed deposits have

been made. In the USPTO proposed rules on deposits (Federal Register, 1987) it is stated that "if a plant itself is claimed, deposit of plant cells can be accepted only if the deposited cells will develop into the plant for which a patent is sought through the exercise of procedures either known in the art or taught in the application disclosure. Seeds may be deposited, but must be deposited in sufficient quantity to insure an adequate and timely supply once a patent is granted. ... If a hybrid variety is claimed, the PTO will take a position that applicant must deposit the parent lines of the hybrid variety unless applicant is able to establish that propagation of the variety can be achieved by micropropagation or other techniques from the hybridized seed or plants grown from such seed. In the latter case, the deposit of the hybrid seed itself would make an adequate deposit. ..."

The deposit of seeds and plant tissue culture has become an established practice. Although there are few depositories world-wide which accept such deposits, there is one in the United States which does.

A decision by the Board of Patent Appeals and Interferences in **Ex parte Allen** (Bd. App. & Int., April, 1987), held that claimed polyploid oysters are

nonnaturally occurring manufactures or compositions of matter within the meaning of 35 U.S.C. 101. The Patent and Trademark Office now considers nonnaturally occurring nonhuman multicellular living organisms, **including animals**, to be patentable subject matter.

Will the USPTO encourage or require the deposit of animal forms to support certain patent applications? It is possible that this will occur. Already the ATCC has received a request from an inventor's attorney to consider accepting oyster larvae to support a patent application in the USPTO.

It is not practical to maintain or make available whole animals, but the maintenance of embryos in a frozen state may be possible. If culturing fertilized ova to the blastula stage as an indicator that growth of the animal would occur is feasible, and would be an acceptable test of viability, it may not be impractical to maintain and make available animal forms. What constitutes "viability" must be defined. This is also coupled with acceptability of statistical probability that the ovum/embryo would be capable of implantation and successful gestation.

To date no animal form has been deposited with a depository.

PROBLEMS THAT ARE LIKELY TO ARISE FOR INDEPENDENT DEPOSITORIES SHOULD ANIMALS BE PATENTED

The patenting of animals could cause problems for a depository if deposit of the animal is required. Currently there is no depository willing to accept the deposit of animals for the following reasons:

1. The cost of facilities and expertise which might be needed to maintain animals would be prohibitive.

2. Adverse publicity which might be associated with maintaining animals for patent purposes could jeopardize a depository's reputation.

3. If it were necessary to maintain the animal, a depository might need to "grow" another sample to prove the replication of the animal. After growth of the animal, disposal might not be acceptable, and, therefore, maintenance of progeny would be necessary.

4. How would a depository make samples of the animal available? Grow more animals?

5. Maintenance of an animal for the current required period of 30 years would not be practical or possible, as the life span of many animals is shorter than 30 years.

The deposit of animal embryos may not present the same difficulties, as long as the embryos can be successfully frozen and recovered. To date at least thirteen species of animal embryos (cattle, mice, rats, rabbits, hamsters, sheep, goats, horses, cats, antelopes, and three species of nonhuman primates) have been successfully frozen and recovered, and many thousands of live young from frozen mice and cattle embryos have been produced (S. Leibo, personal communication). U.S. Patents 4,380,997 and 4,419,986 were issued in 1982 to S. Leibo for the process of freezing animal embryos. Dr. Leibo believes that culturing of animal embryo cells to the blastula stage is a technically feasible and acceptable test for viability. If this is an acceptable viability test, patent depositories may be willing to accept animal embryos for deposit. If deposit of animal forms is necessary for patent purposes, the Patent and Trademark Office should explore the possibilities and develop specific guidelines for such deposits

SUMMARY

The practice of depositing microorganisms to

provide enablement and/or the best mode of practicing an invention has been in place since 1949, although a deposit is not always required. The ability to patent novel life forms created through biotechnology, as held in the **Chakrabarty** case, and the ability to protect plants with a utility patent as held in the **Hibberd** case, has resulted in increased patenting in these areas and thereby increased deposits of microorganisms, cells and plants. It appears that the deposit of microorganisms, plants and similar material in support of a patent application is a well-established practice, though not all problems associated with this practice have been resolved.

The recent announcement by the USPTO that nonnaturally occurring multicellular living organisms, including animals, are patentable, will lead to patenting of animal forms. Though deposit of the animal forms is not a current requirement, it may become necessary. There are problems associated with deposit of animal forms which need to be examined and guidelines developed.

REFERENCES

Ex parte Allen 2. U.S. Patent Quarterly 2d 1425 (Board of Patent Appeals and Interferences). 1987.

In re Argoudelis. U.S. Patent Quarterly 434 F.2d 1390,168 (Court of Customs and Patent Appeals). 1970.

Diamond v. Chakrabarty 206. U.S. Patent Quarterly 193. 1980.

Feldman v. Aunstrup 199. U.S. Patent Quarterly 517 F.2d 1351 (Court of Customs and Patent Appeals). 1975.

Ex parte Hibberd 227. U.S. Patent Quarterly 443 (Board of Patent Appeals and Interferences). 1985.

Leibo, Stanley, Rio Vista International, Inc., San Antonio, Texas, personal communication, November 1987.

In re Lundak 90. U.S. Patent Quarterly 723 F.2d 1216,227. 1985.

Wahl, R.A. 169. U.S. Patent Quarterly 6. 1971.

U.S. Federal Register, Deposit of Biological Materials for Patent Purposes; Advance Notice of Proposed Rulemaking, 52(174), 1987.

Table 1-A

U.S. Depositories and Strains Accepted

DEPOSITORY	KINDS OF CULTURES ACCEPTED	NUMBER OF CULTURES ON HAND	
AMERICAN TYPE CULTURE COLLECTION (ATCC) 12301 Parklawn Drive Rockville, Maryland 20852 Bobbie A. Brandon, Head of Patent Depository	Algae, Animal Viruses, Bacteria, Cell Lines, Fungi, Hybridomas, Oncogenes, Plant Viruses, Plasmids, Plant Tissue Cultures, Phages, Protozoa, Seeds and Yeasts	1949-1965 estimated 1966-1987	500 7,500
AGRICULTURAL RESEARCH CULTURE COLLECTION (NRRL) 1815 North University Street Peoria, Illinois 61604 Mr. James Lyons, Patent Depository	Nonpathogenic cultures of bacteria and fungi that can be preserved by freeze-drying.	1949-1987 estimated	3,000
IN VITRO INTERNATIONAL INC. (IVI) 611 (P) Hammonds Ferry Road Linthicum, Maryland 21090 Patent Depository	Algae, Animal Viruses, Bacteria (and with plasmids), Bacteriophages, Cell Lines, Fungi, Plant Viruses and Protozoa	1983-1987	100

Information provided by personal communication with the depositories.

Table 2-A

Depository Institutions Having Acquired the Status of International Depository Authority

INTERNATIONAL DEPOSITORY AUTHORITY	KINDS OF MICROORGANISMS THAT MAY BE DEPOSITED	FEES
AGRICULTURAL RESEARCH CULTURE COLLECTION (NRRL) 1815 North University Street Peoria, Illinois 61604 United States of America	Progeny of strains of non-pathogenic agriculturally and industrially important bacteria, yeast, molds, and *Actinomycetales*.	Applicable to patent cultures deposited after October 30, 1983. No fee charged for cultures on deposit or received before that date. (a) Deposit of each strain (payable at time of deposit) US$ 500 (b) Distribution of all related cultures 20 Checks, in US dollars, should be made payable to the Agricultural Research Service, United States Department of Agriculture. United States Department of Agriculture laboratories and designated cooperators are exempt from payment of fees.
AMERICAN TYPE CULTURE COLLECTION (ATCC) 12301 Parklawn Drive Rockville, Maryland 20852 United States of America	Algae, animal and plant viruses, bacteria, bacteriophages, fungi, plant tissue cultures, plasmids, protozoa, seeds, and yeasts. The ATCC must be informed of the physical containment level required for experiments using the host vector system, as described in the 1980 National Institutes of Health Guidelines for Research involving Recombinant DNA Molecules (i.e., P1, P2, P3 or P4 facility). The ATCC, for the time being, will accept only those hosts containing plasmids which can be worked in a P1 or P2 facility. Certain animal viruses may require viability testing in an animal host, which the ATCC may be unable to provide. In such case, the deposit cannot be accepted. Plant viruses which cannot be mechanically inoculated also cannot be accepted.	(a) Storage US$ 870 — if the right under Rule 11.4(*g*) to be notified of the furnishing of samples is waived 570 (b) Issuance of a viability statement — bacteria (without plasmids) 100 — fungi (including yeasts) 100 — protozoa 100 — algae 100 — animal cell cultures (including hybridoma lines) fee must be decided — animal and plant viruses on an individual basis — bacteria (with plasmids) (c) Furnishing of a sample under Rules 11.2 and 11.3 (per sample) *ATCC Cultures* 12.00 to 72.00
CENTRAALBUREAU VOOR SCHIMMELCULTURES (CBS) Oosterstraat 1 Postbus 273 NL-3740 AG Baarn Netherlands	Fungi, including yeasts; actinomycetes, bacteria other than actinomycetes.	(a) Storage Hfl. 2.000 — if the depositor waives the right under Rule 11.4(*g*) to be notified of the furnishing of samples 1.500 (b) Issuance of a viability statement 150 (c) Furnishing of a sample — to a scientific institution 45 — in other cases 90 (d) Communication of information under Rule 7.6 40 (e) Delivering of attestation pursuant to Rule 8.2 40

INTERNATIONAL DEPOSITORY AUTHORITY	KINDS OF MICROORGANISMS THAT MAY BE DEPOSITED	FEES
COLLECTION NATIONALE DE CULTURE DE MICRO-ORGANISMES (CNCM) Institut Pasteur 28 rue du Dr Roux 75724 Paris Cedex 15 France	Bacteria (including actinomycetes), bacteria containing plasmids; filamentous fungi and yeasts, and viruses at the P1 and P2 level. The CNCM reserves the possibility of refusing any microorganism for security reasons: specific risks to human beings, animals, plants and the environment.	(a) Storage — bacteria, fungi and yeasts, lyophilized or lyophilizable: F Fr 3,500 — all other acceptable cultures: case-by-case fee (b) Furnishing of samples (except in specific cases); (plus cost of transport): 600 (c) Issuance of a viability statement: — requiring a viability test (except in specific cases): 600 — in other cases: 100 (d) Communication of information or issue of an attestation: 200 Fees are subject to Value Added Tax according to French provisions currently in force.
CULTURE COLLECTION OF ALGAE AND PROTOZOA (CCAP) Freshwater Biological Association Windermere Laboratory The Ferry House Far Sawrey Ambleside, Cumbria LA22 OLP United Kingdom and Scottish Marine Biological Association Dunstaffnage Marine Research Laboratory P.O. Box 3 Oban, Argyll PA34 4AD United Kingdom	(i) freshwater and terrestrial algae and free-living protozoa (Freshwater Biological Association); and (ii) marine algae, other than large seaweeds (Scottish Marine Biological Association).	(a) Storage of each microorganism: £ 275 (b) Issuance of a Viability Statement in those cases in which, in accordance with Rule 10.2, a fee may be charged: 50 (c) Furnishing of a sample in accordance with Rule 11.2 or 11.3 (plus the actual cost of carriage): 10 (d) Delivering an attestation in accordance with Rule 8.2: 10 Fees are subject to Value Added Tax, where applicable.
CULTURE COLLECTION OF THE COMMONWEALTH MYCOLOGICAL INSTITUTE (CMI CC) Ferry Lane Kew, Surrey TW9 3AF United Kingdom	Fungal isolates, other than known human and animal pathogens and yeasts, that can be preserved without significant change to their properties by the methods of preservation in use.	(a) Storage of each isolate of microorganism: £ 400 (b) Issuance of a viability statement in those cases in which, in accordance with Rule 10.2, a fee may be charged: 50 (c) Furnishing of a sample in accordance with Rule 11.2 or 11.3: 35 (d) Delivering an attestation in accordance with Rule 8.2: 10 Fees paid within the United Kingdom are subject to Value Added Tax at the current rate.

INTERNATIONAL DEPOSITORY AUTHORITY	KINDS OF MICROORGANISMS THAT MAY BE DEPOSITED	FEES
DEUTSCHE SAMMLUNG VON MIKROORGANISMEN (DSM) Gesellschaft fur Biotechnologische Forschung mbH Grisebachstr. 8 3400 Gottingen Federal Republic of Germany	Bacteria, including actinomycetes, fungi, including yeasts, bacteriophages, except any kinds pathogenic to humans or animals. Phytopathogenic kinds are accepted, *except:* *Erwinia amylovora; Coniothyrium fagacearum, Endothia parasitica; Gloeosporium ampelophagum, Septoria musiva; Synchytrium endobioticum.*	(a) Storage DM 950 (b) Issuance of a viability statement — if the depositor seeking a viability statement has also requested a viability test 80 — in other cases 30 (c) Furnishing of a sample 60 (d) Communication of information under Rule 7.6 30 Fees are expressed net of Value Added Tax payable under the provisions in force in the Federal Republic of Germany. Extra charges are payable for dispatch by air.
EUROPEAN COLLECTION OF ANIMAL CELL CULTURES* (ECACC) Vaccine Research and Production Laboratory Public Health Laboratory Service Centre for Applied Microbiology and Research Porton Down Salisbury, Wiltshire SP4 OJG United Kingdom *Formerly known as the National Collection of Animal Cell Cultures (NCACC).	Cell lines that can be preserved without significant change to or loss of their properties by freezing and long term storage; viruses capable of assay in tissue culture. A statement on their possible pathogenicity to man and or animals is required at the time of deposit. Up to and including ACDP Category 3* can be accepted for deposit. *Advisory Committee on Dangerous Pathogens.	(a) Storage £ 600 800* (b) Issuance of a Viability Statement in those cases in which, in accordance with Rule 10.2, a fee may be charged 30 100* (c) Furnishing of a sample in accordance with Rule 11.2 or 11.3 50 80* Fees are payable to the Public Health Laboratory Service Board. Fees paid within the United Kingdom are subject to Value Added Tax at the current rate. *Fees in regard to viruses.
FERMENTATION RESEARCH INSTITUTE (FRI) 1-3, Higashi 1-chome Yatabe-machi Tsukuba-gun, Ibaraki-ken 305 Japan	Fungi, yeast, bacteria and actinomycetes, *except:* — microorganisms having properties which are or may be dangerous to health or the environment; — microorganisms which need the physical containment level P2, P3 or P4 required for experiments, as described in the 1979 Prime Minister's Guideline for Research Involving Recombinant DNA Molecules.	(a) Storage: — original deposit Yen 170.000 — new deposit 9.700 (b) Attestation referred to in Rule 8.2 1.800 (c) Viability statement: — if the depositor, when requesting the issuance of a viability statement, also requested a viability test 5.900 — in other cases 1.800 (d) Furnishing of a sample 6.900 (e) Communication of information under Rule 7.6 1.300
IN VITRO INTERNATIONAL, INC. (IVI) 611(P) Hammonds Ferry Road Linthicum, Maryland 21090 United States of America	Algae, bacteria with plasmids, bacteriophages, cell cultures, fungi, protozoa and animal and plant viruses. Recombinant strains of microorganisms will also be accepted, but IVI must be notified in advance of accepting the deposit of the physical containment level	(a) Cultures deposited during a 12-month period: 1 to 5 US$ 610 each 6 to 10 550 each 11 to 15 480 each (b) Samples of cultures furnished

INTERNATIONAL DEPOSITORY AUTHORITY	KINDS OF MICROORGANISMS THAT MAY BE DEPOSITED	FEES
IVI *(continued)*	required for the host vector system, as prescribed by the National Institutes of Health Guidelines. At present, IVI will accept only hosts containing recombinant plasmids that can be worked in a P1 or P2 facility.	to the public 1 to 5 30 each 6 to 10 25.50 each 11 to 15 25 each (c) Viability test 60
MEZOGAZDASAGI ES IPARI MIKROORGANIZMUSOK MAGYAR NEMZETI GYUJTEMENYE (MIMNG) [National Collection of Agriculture and Industrial Microorganisms (NCAIM)] Kerteszeti Egyetem, Mikrobiologiai Tanszek (Department of Microbiology, University of Horticulture) Somloi ut 14-16 H-1118 Budapest Hungary	— Bacteria (including Streptomyces) except obligate human pathogenic species *(e.g.*, Corynebacterium diphtheriae, Mycobacterium leprae, Yersinia pestis, etc.) — Fungi, including yeasts and moulds, except some pathogens (Blastomyces, Coccidioides, Histoplasma, etc.), as well as certain basidiomycetous and plant pathogenic fungi which cannot be preserved reliably. Apart from the above-mentioned, the following may not, at present, be accepted for deposit: — viruses, phages, rickettsiae, — algae, protozoa, — cell lines, hybridomas.	(a) Storage of the microorganisms in accordance with Rule 9.1 Ft 15,000 (b) Issuance of an attestation in accordance with Rule 8.2 500 (c) Issuance of a viability statement, except in the cases provided for under Rule 10.2*(e)* 1,500 (d) Furnishing of a sample in accordance with Rule 11.2 or 11.3 2,000 plus cost of transport (e) Communication of information under Rule 7.6 500
NATIONAL BANK FOR INDUSTRIAL MICROORGANISMS AND CELL CULTURES (NBIMCC) 125 Lenin Blvd. Block 2 Sofia, Bulgaria	Bacteria, actinomycetes, microscopic fungi, yeasts, microscopic algae, animal cell lines, animal viruses and plasmid-containing microorganisms	— for the initial deposit and 30 years' storage Leva 1,000 — upon prolongation of the deposit for every next five-year period 150 — for the furnishing of a sample of a deposited strain of microorganism 100
NATIONAL COLLECTION OF INDUSTRIAL BACTERIA (NCIB) c/o The National Collections of Industrial and Marine Bacteria Ltd. Torry Research Station P.O. Box 31 135 Abbey Road Aberdeen AB9 8DG United Kingdom	(a) Bacteria, including actinomycetes, that can be preserved without significant change to their properties by liquid nitrogen freezing or by freeze-drying (lyophilisation), and which are allocated to a hazard group no higher than Group 2 as defined by the UK Advisory Committee on Dangerous Pathogens (ACDP); (b) Plasmids, including recombinants, either (i) cloned into a bacterial or actinomycete host, or (ii) as naked DNA preparations Notwithstanding the foregoing, the NCIB reserves the right to refuse to accept any material for deposit which in the opinion of the Curator presents an unacceptable hazard or is technically too difficult to handle.	(a) Storage £ 225 (b) Issuance of a Viability Statement, where a fee may be charged 40 (c) Furnishing of a sample in accordance with Rule 11.2 or 11.3 (i) to commercial organizations 18+ actual cost of carriage (ii) to non-profit-making organizations 9+ actual cost of carriage

INTERNATIONAL DEPOSITORY AUTHORITY	KINDS OF MICROORGANISMS THAT MAY BE DEPOSITED	FEES
NATIONAL COLLECTION OF TYPE CULTURES (NCTC) Central Public Health Laboratory 61 Colindale Avenue London NW9 5HT United Kingdom	Bacteria that can be preserved without significant change to their properties by freeze-drying and which are pathogenic to man and/or animals.	(a) Storage £ 250 (b) Issuance of a Viability Statement in those cases in which, in accordance with Rule 10.2, a fee may be charged 25 (c) Furnishing of a sample in accordance with rule 11.2 or 11.3 40 Fees paid within the United Kingdom are subject to Value Added Tax at the current rate.
NATIONAL COLLECTION OF YEAST CULTURES (NCYC) Food Research Institute Colney Lane Norwich, Norfolk NR4 7UA United Kingdom	Yeasts other than known pathogens that can be preserved without significant change to their properties by freeze-drying or, exceptionally in active culture.	(a) Storage £ 240 (b) Issuance of a Viability Statement in those cases in which, in accordance with Rule 10.2, a fee may be charged 25 (c) Furnishing of a sample in accordance with Rule 11.2 or 11.3 plus actual cost of carriage 10 Fees paid within the United Kingdom are subject to Value Added Tax at the current rate.

Information excerpted from Industrial Property, 1987, pp. 25-30, 147-148, 363-364.

Table 3-A

Release of Patent Microorganism Deposited In Fermentation Research Institute, Japan

		Release under Budapest deposit system
Related laws etc.		Budapest Treaty and related regulations Regulations relating to deposit etc. of microorganisms under Budapest Treaty (Ministry of International Trade and Industry Notification No. 177 of 1981) Gist of enforcement of regulations relating to deposit etc. of microorganisms under Budapest Treaty (56 FRI No.220 of 1981)
Manner of indicating deposited microorganism requested for release	In Japanese characters	
	In Roman letters	FERM BP —XXXX
Documents required at time of application for release		Request for the furnishing under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure — one copy One of the following: Form No. 8 BP Regulation 11.2 (i) Form No. 9 BP Regulation 11.2 (ii) Form No. 10 BP Regulation 11.3 (a) Form No. 11 BP Regulation 11.3 (b) Statement of payment for the charge Style No. 18 — one copy (Power of attorney)
Payment for the charge of release		Patent revenue stamps or cash (Bank transfer in the case of payment from overseas only)
Usable languages		Japanese, English and French
Who can request release		(1) International Industrial Property Offices (2) Depositor (Application using Form No. 8) (3) Person having consent of depositor (Application using Form No. 9) (4) Person legally entitled (Application using Form No. 10 or 11)
Time when release becomes possible		In the case of (1) above: at any time In the case of (2) above: at any time In the case of (3) above: at any time In the case of (4) above: Depending on country may be after patent public disclosure, after publication of patent application for opposition or some other time. (Certification of concerned Industrial Property Office is required; provided, however, that this does not apply when notification of the strain number has been received from the agency concerned. In such case the application for release is made using Form No. 11.)
Who may take procedure		Person requesting release or his agent
Comments		Documents translated into English are available for requesting release to be made from overseas. The applicant need only fill these in English or French. The application for release must be in compliance with that specified by the BP Treaty.

Comments *(continued)*

In a case where certification is required, the certificate must be one issued by the Industrial Property Office which handled the application concerned.

Where the applicant or his agent has a foreign nationality, his signature may be substituted for his seal.

Although an application for release based on EPC Rule 28 and certified by EPO is valid, a separate application for release based on the BP treaty is additionally necessary.

(This requirement is satisfied by attaching an EPO certified petition at the certification column)

Certification by an Industrial Property Office unrelated to the application concerned is invalid.

When a sample of the microorganism concerned has been delivered to the person requesting release, the depositor is notified of such fact.

Information excerpted from Bulletin of the Japan Federation for Culture Collections 2(1), 1986

APPENDIX A

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 1

Deposit of Biological Materials for Patent Purposes;

Advance Notice of Proposed Rulemaking

"Deposit of Biological Material

"1.200 Biological material.

"For the purpose of these regulations pertaining to the deposit of biological material for patent purposes, the term biological material shall include material that is capable of self-replication either directly or after insertion into a host. Representative examples include bacteria, fungi including yeasts, algae, protozoa, cell lines, plant tissue cells and seeds. Viruses, vectors, cell organelles and other non-living material existing in and reproducible from a living cell may be deposited by deposit of the host cell capable of reproducing the non-living material. Materials analogous to conventional chemical compounds such as proteins and enzymes are not subject to these regulations.

"1.201 Need to make a deposit.

"(a) Where a claimed invention is, or relies on, a biological material, the requirements of the first and second paragraphs of 35 U.S.C. 112 apply. Applicant is required to comply with these requirements in the written description of the invention, which may include reference to known and readily available biological material. If the written description does not meet the requirements of 35 U.S.C. 112, the specification may be supplemented by a deposit of samples of the biological material necessary to meet those requirements in a depository and under conditions complying with these regulations.

"(b) Biological material need not be deposited if it is known and readily available to the public or can be made or isolated in a reproducible manner from known and readily available material. Biological material will be considered to be known and readily available to the public if samples of the biological material are known and accessible without restriction to those who desire to obtain and test the biological

material. Samples will be considered to be accessible even though some requirement of law or regulation of the United States or of the country in which the depository institution is located permits access to the material only under conditions imposed for safety, public health or similar reasons.

"(c) The reference to a specific organism or other biological material in a specification disclosure does not create any presumption that the specific material is necessary to satisfy one or more requirements of 35 U.S.C. 112 or that a deposit in accordance with these regulations is required.

"1.202 Acceptable depository.

"(a) A deposit may be made in any International Depositary Authority (IDA) as established under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

"(b) A deposit may be made in any depository recognized to be suitable by the Office. Suitability will be determined by the Commissioner

on the basis of the administrative and technical competence, and agreement of the depository to comply with the terms and conditions applicable to deposits for patent purposes. The Commissioner may seek the advice of impartial consultants from the biotechnology industry on the suitability of a depository. The depository must:

"(1) Have a continuous existence;

"(2) Exist independent of the control of the depositor;

"(3) Possess the staff and facilities sufficient to enable it to examine the viability of a deposit and store it in a manner which ensures that it is kept viable and uncontaminated;

"(4) Provide for sufficient safety measures to minimize the risk of losing biological material deposited with it;

"(5) Be impartial and objective; and

"(6) Furnish samples of the deposited material in an expeditious and proper manner.

"(c) If any depository under (a) or (b) defaults or discontinues the performance of any of

the tasks it should perform, the Office will recognize as a substitute in any pending application or patent a viable deposit made with an IDA or depository recognized to be suitable by the Office which is transferred to said depository from the defaulting depository in the manner required for replacing a deposit under 1.204.

"(d) A depository seeking status under paragraph (b) of this section must direct a communication to the Commissioner which shall:

"(1) Indicate the name and address of the depository to which the communication relates;

"(2) Contain detailed information as to the capacity of the depository to comply with the requirements of paragraph (b) of this section, including information on its legal status, scientific standing, staff and facilities.

"(3) Indicate the depository intends to be available, for the purposes of deposit, to any depositor under these conditions;

"(4) Where the depository intends to accept for deposit only certain kinds of

biological material, specify such kinds;

"(5) Indicate the amount of any fees that the said depository will, upon acquiring the status of suitable depository under paragraph (b) of this section, charge for storage, viability statements and furnishing of samples of the deposit.

"(e) Once a depository is recognized to be suitable by the Commissioner or has defaulted or discontinued its performance under this section, notice thereof will be published in the Official Gazette of the Patent and Trademark Office.

"1.203 **Time of making an original deposit**

"(a) An original deposit may be made at any time before filing an application for patent or during pendency of the application for patent pursuant to a requirement that will be made by the examiner no later than the date the Notice of Allowance and Issue Fee Due is mailed.

"(b) When the original deposit is made in a depository defined in Sections 1.202 (a) or (b) after the effective filing date of an application for patent, a verified statement will be required from a person in a position to corroborate the

fact that the biological material described in the application as filed is the same biological material which is deposited in the depository defined in Sections 1.202 (a) or (b).

"1.204 Replacement of deposit.

"(a) Where a depository possessing the original deposit cannot furnish samples of the deposit for any reason, the depository shall, promptly after having noted its inability to furnish samples, notify the depositor of such inability, indicating the cause thereof, and the depositor shall be required to make a new deposit of the biological material which was originally deposited within three months of receiving notification that the depository cannot furnish samples. The replacement shall be made in the same depository as the original deposit except:

"(1) Where the original depository has lost its status under Sections 1.202 (a) or (b) or no longer carries out its obligations applicable to the involved deposit; or

"(2) Where the depository for health or other legitimate reasons is unable to

provide samples to requesters outside of the jurisdiction where the depository is located.

"(b) An applicant or patent owner shall notify the Office in writing as soon as reasonably possible after a replacement deposit is made in each application or patent affected. This notification shall state the name and address of the depository, the accession number for the deposit, the date of making the deposit, the results of a viability test (as provided for in Section 1.206), the reason for making the replacement deposit, and a statement that the replacement deposit is to the best of the depositor's knowledge identical to the original deposit. The notification shall be placed in each application or patent file.

"(c) A depositor's failure to replace a deposit within three months after learning or after receiving written notice from a depository that a replacement is needed may cause the application or patent involved to be treated in any Office proceeding as if no deposit were made.

"(d) In the event a deposit is replaced, the

PTO will apply a rebuttable presumption of an identity between the original and the replaced sample where the application or patent making reference to the deposit is relied upon during any Office proceeding.

"1.205 Term of deposit.

"A deposit shall be made for a term of at least thirty (30) years after the date of a viable deposit and at least five (5) years after the most recent request for the furnishing of a sample of the deposited biological material was received by the depository. In any case, samples must be stored under agreements that would make them available beyond the enforceable life of the patent for which the deposit was made.

"1.206 Viability of deposit.

"(a) A deposit of biological material must be viable at the time of deposit and during the term of deposit. Viability may be tested by the depository or by another provided the material tested is received from the depository. The test must conclude only that the deposited material is capable of reproduction. No evidence is necessarily required relative to the ability of

the deposited material to perform any function described in the patent application.

"(b) A viability statement for each deposit not made under the Budapest Treaty must be filed in the application and must contain:

"(1) Name and address of the depository;

"(2) Name and address of the depositor;

"(3) The date of deposit;

"(4) The identity of the deposit and the accession number given by the depository;

"(5) The date of the viability test;

"(6) The procedures used to obtain a sample if the test is not done by the depository; and

"(7) A statement that the deposit is capable of reproduction.

"(c) If a viability test indicates that the deposit is not viable upon receipt, or the examiner cannot, for scientific or other valid reasons, accept the statement of viability received from the applicant, the examiner shall proceed as if no deposit has been made. The examiner will accept the conclusion set forth in a

viability statement issued by a depository recognized under Sections 1.202 (a) and (b).

"1.207 Furnishing of samples.

"The deposit must be made under conditions that assure that:

"(a) Access to the deposit will be available during pendency of the patent application making reference to the deposit to one determined by the Commissioner to be entitled thereto under Sections 1.14 and 35 U.S.C. 122, and

"(b) All restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent.

"(c) Upon request, the Office will certify whether a deposit has been stated to have been made under conditions which make it available to the public as of the issue date of the patent grant provided the request contains:

"(1) The name and address of the depository;

"(2) The accession number given to the deposit;

"(3) The patent number and issue date of the patent referring to the deposit; and

"(4) The name and address of the requesting

party.

"1.208 **Examination procedures.**

"(a) The examiner shall determine in each application for an invention if a deposit is needed, in case one has not been made, or if a deposit actually made is acceptable for patent purposes. A deposit accepted in any depository under the Budapest Treaty shall be accepted for patent purposes if made under conditions complying with Section 1.207 (b). If a deposit is required and has not been made in accordance with these regulations, the examiner shall in an Office action reject the affected claims in the application under the appropriate provision of 35 U.S.C. 112, explaining why a deposit is needed and/or why a deposit actually made cannot be accepted.

"(b) The applicant shall respond to a rejection under paragraph (a) of the section by--

"(1) Making an acceptable deposit or assuring the Office in writing that an acceptable deposit will be made on or before the date of payment of the issue fee or,

"(2) Establishing that the involved biological material is known and readily available to the public or,

"(3) Arguing why a deposit is not required under the circumstances of the application considered. Other replies to the examiner's action shall be considered non-responsive. The rejection will be repeated until either paragraph (b)(1) or (b)(2) of this section is satisfied or the examiner is convinced that a deposit is not required.

"(c) If an application is otherwise in condition for allowance except for the required deposit and the Office has received a written assurance that an acceptable deposit will be made on or before payment of the issue fee, the Office will mail to the applicant a Notice of Allowance and Issue Fee Due together with a requirement that the required deposit be made within three months. The period for satisfying this requirement is extendable under 37 CFR 1.136. Failure to make the required deposit in accordance with this

requirement will result in abandonment of the application for failure to prosecute.

"(d) For each deposit made pursuant to these regulations, the specification shall contain:

"(1) Accession number for the deposit;

"(2) Date of the deposit;

"(3) Taxonomic description of the deposit; and

"(4) Name and address of the depository."

U.S. Federal Register, 1987; 52(174), 34080-34093.

DEPOSIT REQUIREMENTS FOR MICROORGANISMS, PLANTS AND ANIMALS IN U. S. PATENT CLAIMS

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